

### **DETAILED ACTION**

Applicant's cancellation of claims 2, 3, 25-50 submitted 07/19/2010 has been noted and entered.

#### ***Claim Rejections - 35 USC § 112***

1. Claims rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites the limitation "...detecting the position of the first marker using a second tracking system in an operating theatre, the second tracking system having a second reference frame; and using the mapping to register the first image with the detected position of the body part in the second reference frame". There is no support in the disclosure as originally filed for this limitation.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 4-7, 9-11, 13, 19, 20, 23, 24, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka et al (US 6,640,127, henceforth referred to as Kosaka) in view of Carson (US 2002/0198451).

Kosaka discloses a method for generating a registered image of a body part of a patient for use in a computer aided surgical procedure, the method comprising: attaching a marker detectable by a tracking system to the body part prior to any surgical steps of the surgical procedure, the tracking system having a reference frame; detecting the position of the marker in the reference frame; capturing at least a first image of the body part using an imaging system; obtaining an indication of the position of the first image relative to the reference frame of the tracking system; and determining a mapping to bring the first image into registration with the position of the body part, displaying the registered image during the computer aided surgical procedure (col.24, 18-32; fig. 8, fig. 19) wherein the first image includes the marker and at least a part of

the body part, and wherein the position of the marker is detected when the first image is captured thereby providing the indication (fig. 13) and the imaging system is an x-ray or MR system (abstract) and wherein the first image includes the marker and at least a part of the body part and wherein the position of the marker is detected when the first image is captured. Kosaka also discloses attaching a second marker to the body of the patient and tracking said second marker (fig. 17).

Kosaka fails to disclose placing a marker on the imaging device and using the position of the marker on the imaging device in determining the position of the image for bringing the image into registration with the position of the body part and the surgical procedure being an orthopaedic procedure and attaching the markers to a bone or detecting the position of the first marker using a second tracking system in an operating theatre, the second tracking system having a second reference frame; and using the mapping to register the first image with the detected position of the body part in the second reference frame.

Carson discloses an image guided orthopaedic procedure wherein markers are attached to the bones of the patient (fig. 1, fig. 2, [0010]) and the markers are detectable using radio frequencies (clm. 6). Carson also discloses placing a marker on an imaging device and using the position of the marker on the imaging device in determining the position of an image for bringing the image into registration with the position of a body part (fig. 1 [0015], [0030]). Carson also discloses detecting the position of the first marker using a second tracking system in an operating theatre, the second tracking system having a second reference frame; and using the mapping to register the first

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image with the detected position of the body part in the second reference frame ([0008], [0025], [0054]).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Kosaka's method by using the system in an orthopaedic procedure and attaching the markers to the bones of a patient, as taught by Carson, in order enable image guidance of the surgeon during such surgeries. It would also have been obvious to one having ordinary skill in the art at the time of invention to modify Kosaka's method by placing a marker on the imaging device and using the position of the marker on the imaging device in determining the position of the image for an bringing the image into registration with the position of the body part, as taught by Carson, in order to increase the accuracy of the information provided by the tracking system during surgery.

Regarding claim 11, although both Kosaka and Carson fail to explicitly disclose the patient being in a standing position, on of ordinary skill in the art would have recognized that the position of the marker would be detected with the patient in whatever position required by the circumstances of the procedure, including in a standing position.

Regarding claim 13, Carson discloses the use of X-ray as an imager during a procedure [0005] as well as attaching a marker to the imager used during said procedure (fig. 1) and determining the position of the imager in the reference frame of the tracking system used in the procedure ([0015]. [00300]). It would have been obvious to one having ordinary skill in the art at the time of invention to attach a marker

to an x-ray device and to track that x-ray device during a procedure since Carson discloses performing such a step with an imager and that x-ray devices are known imagers for use in procedures.

2. Claims 14, 15, 16, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of Carson as applied to claim 10 above, and further in view of Cosman (US 2002/0188194).

The Kosaka and Carson combination discloses the method substantially as claimed, including tracking the position of an imaging device during imaging but fails to disclose generating a second x-ray image in a second direction.

Cosman discloses attaching markers 40a, 40b, 40c to an imaging device 191 during a medical procedure, attaching markers 30, 31, 32 to the patient support, determining the position of the patient support in a reference coordinate system and determining the position of the imaging device within the coordinate system of the tracking system [0104]. Cosman also discloses moving the support on which the patient lays and imaging the patient from different positions, moving x-ray source relative to the patient and determining the position of the x-ray source relative to the coordinate system of the tracking device [0025], [0030]).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of the Kosaka and Carson combination by attaching markers to the imaging device, as taught by Cosman, in order to enable the determination of the position of the patient relative to the imaging device. It would also

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have been obvious to one of ordinary skill in the art to move the support on which the patient lays and image the patient from different positions to insure proper positioning of the patient and proper registration of the images.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of Carson as applied to claim 7 above, and further in view of Song (US 6,942,667).

The Kosaka and Carson combination discloses the method substantially as claimed but fails to disclose percutaneously implanting the marker.

Song discloses the percutaneous implantation of markers to bones (col. 2 lines 32-43).

It would have been obvious to one having ordinary skill in the art at the time of invention to modify the method of the Kosaka and Carson combination by percutaneously implanting the marker to the body, as taught by Song, in order to reduce the trauma associated with the procedure.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of Carson as applied to claim 1 above, and further in view of Govari et al (US 2003/0023161, henceforth referred to as Govari).

The Kosaka and Carson combination discloses the method substantially as claimed but fails to disclose a wireless magnetic tracking system.

Govari discloses a wireless magnetic tracking system for medical applications.

It would have been obvious to one having ordinary skill in the art at the time of invention to modify the method of the Kosaka and Carson combination by providing wireless magnetic means to track the markers, as taught by Govari, in order to increase versatility of the method.

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of Carson and Cosman as applied to claim 14 above, and further in view of Schweikard et al (US 6,144,875, henceforth referred to as Schweikard).

The Kosaka, Carson and Cosman combination discloses the method substantially as claimed but fails to disclose two x-rays sources at different positions.

Schweikard discloses using an x-ray device comprising two x-ray sources 30, 32 located at different positions (fig. 2) for tracking motion of a patient.

It would have been obvious to one having ordinary skill in the art at the time of invention to modify the method of the Kosaka, Carson and Cosman combination by providing an x-ray device comprising two x-ray sources 30, 32 located at different positions, as taught by Schweikard, in order to improve the tracking capabilities of the device.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of Carson and Cosman as applied to claim 14 above, and further in view of Schuetz (US 6,206,566).

The Kosaka, Carson and Cosman combination discloses the method substantially as claimed but fails to disclose generating a three dimensional image from two images.

Schuetz discloses generating a three dimensional images from two dimensional images.

It would have been obvious to one having ordinary skill in the art at the time of invention to modify the method of the Kosaka, Carson and Cosman combination by generating a three dimensional images from two dimensional images, as taught by Schuetz, in order provide three dimensional images for viewing to the surgeon.

### ***Response to Arguments***

Applicant's arguments filed 04/26/2011 have been fully considered but they are not persuasive. Regarding applicant's argument that the applied references fail to disclose the newly added limitation of detecting the position of the first marker using a second tracking system in an operating theatre, the second tracking system having a second reference frame; and using the mapping to register the first image with the detected position of the body part in the second reference frame, Examiner disagrees. Carson also discloses detecting the position of the first marker using a second tracking system in an operating theatre, the second tracking system having a second reference frame; and using the mapping to register the first image with the detected position of the body part in the second reference frame ([0008], [0025], [0054]).



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAUREL J. SELKIN whose telephone number is (571)270-3813. The examiner can normally be reached on M-R 6:00 a.m.-4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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